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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/683,583 | 10/09/2003 | Larry Bock | 40-001210US | 7722 |
| 22798 | 7590 | 02/03/2006 | EXAMINER | |
| QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501 | | | LUNDGREN, JEFFREY S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1639 | |

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 10/683,583 | Applicant(s) BOCK ET AL. | |
| | Examiner Jeffrey S. Lundgren | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-81 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 16, are drawn to a method of detecting a component of interest, classified in class 435, subclass 5.
- II. Claims 10-15, are drawn to a nanosensor array for detecting a change in charge, classified in class 435, subclass 6.
- III. Claim 17, is drawn to a glucose nanosensor, classified in class 435, subclass 7.6.
- IV. Claims 18-28, are drawn to a method of measuring one or more cellular responses, classified in class 435, subclass 7.2.
- V. Claims 29-39, are drawn to a detection system, classified in class 977, subclass 762.
- VI. Claims 40-44, are drawn to a method of measuring cellular response to a test compound, classified in class 435, subclass 7.21.
- VII. Claim 45, is drawn to an intracellular detection device, classified in class 435, subclass 7.2.
- VIII. Claim 46, is drawn to a method of detecting a component of interest, classified in class 977, subclass 703.
- IX. Claims 47-52, is drawn to an array, classified in class 977, subclass 707.
- X. Claim 53-62, is drawn to a method of detecting one or more cellular components, classified in class 977, subclass 703.
- XI. Claims 63-67, are drawn to an apparatus, classified in class 977, subclass 730.
- XII. Claims 68-71, are drawn to a method of detecting an analyte at multiple concentrations, classified in class 137, subclass 814.
- XIII. Claims 72, a microfluidic device, classified in class 137, subclass 814.
- XIV. Claim 73-75, are drawn to a method of amplifying a field effect signal, classified in class 977, subclass 711.
- XV. Claims 76-78, are drawn to a field effect transistor, classified in class 257, subclass 20.

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XVI. Claim 79, is drawn to a method of analyzing a single binding event, classified in class 977, subclass 700.

XVII. Claims 80 and 81, are drawn to a method of preparing a functionalized nanowire array, classified in class 977, subclass 701.

The inventions are distinct, each from the other because of the following reasons:

Groups II, III, V, VII, IX, XI, XIII, and XV, and Groups I, IV, VI, VIII, X, XII, XIV, XVI and XVII, are related as product and process of use or making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using or making the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, nanosensor array of Group II can be made or used as taught by Chao et al., U.S. Patent No. 6, 733, 828 B2, issued on May 11, 2004, filed January 29, 2002, and the method of measuring the cellular response of Group VI, can be practiced with the device of Lee et al., U.S. Patent Appl. Pub. No. 2004/0038307, having priority to July 1, 2002¹. Further, there are multiple ways to make the claimed devices/apparatus of Groups II, III, V, VII, IX, XI, XIII, and XV, in addition to those taught by either Chao or Lee, such as the inventions of any one or more of Groups I, IV, VI, VIII, X, XII, XIV, XVI and XVII.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because the method claims as presented constitute patently distinct inventions, such as the inventions of Groups I, IV, VI, VIII, X, XII, XIV, XVI and XVII. Specifically, the inventions as defined above are physically and/or functionally distinct, wherein the practice of one invention does not require the other. This is also applicable to products/apparatus of the inventions of Groups II, III, V, VII, IX, XI, XIII, and XV.

For these reasons, Groups I-XVII, are considered distinct inventions.

Further, a search and examination of more than one of the methods as claimed in one patent application would result in an undue burden on the Office. The searches required for the

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examination of any two groups are not co-extensive, the classifications are different, and the subject matter between the groups is largely divergent. For example, while the nanosensor array of Group II (a method of measuring a cellular response) is anticipated by Chao (see claims 1 and 21, and Detailed Description of the Invention), the method of Group I is not necessarily anticipated or fairly suggested by the same teaching. While the device of Chao is useful for applications in the electronics and optics arts and is made by methods different than those of Applicants' disclosure, it does not necessarily relate to the method as claimed in Group I (see col. 1, lines 1-55). Further, although the method of measuring a cellular response to a test compound in Group VI is taught by Lee, the intracellular response detection device as claimed is not necessarily taught by Lee, as Lee does not require that the wire extend through the cellular membrane (see claims 54 and 71 of Lee).

Accordingly, restriction of the groups as defined above is deemed proper.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

- A. the "*component of interest*" – No matter which group Applicants elect, Applicants should elect a single component of interest (e.g., enzyme, nucleic acid, etc.);
- B. the "*enzymatic substrate*" – No matter which group Applicants should elect, Applicants should elect a single enzymatic substrate (e.g., protein, oligonucleotide, etc.);
- C. the "*functional group*" – No matter which group Applicants should elect, Applicants should elect a single functional group (e.g., hairpin turn, etc.); and

¹ Each of Chao and Lee are considered to anticipate the inventions of Groups II and VI, respectively, under 35 U.S.C. § 102(e).

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- D. the “*cellular response*” – No matter which group Applicants should elect, Applicants should elect a single cellular response (e.g., cell death, cell proliferation, etc.).

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete, the reply must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.43). Because the above restriction/election requirement is complex, a telephone call to Applicants to request an election was not made. See MPEP § 812.01.

Correction of Inventorship

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Consideration of Rejoinder

The Examiner has required restriction between product and process claims. Where Applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise **include all the limitations of the allowable product claim** will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Time for Reply

Applicant is reminded that 1-month (not less than 30 days) shortened statutory period will be set for reply when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program. M.P.E.P. § 809.02(a).

Conclusions

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsius verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDE/JSL

Jon D. Epperson

A handwritten signature in black ink, appearing to be 'Jon D. Epperson', with a long horizontal stroke extending to the right.